

**Statement of the American Academy of Nursing  
And the American Organization of Nurse Executives  
For the Food and Drug Administration  
Regarding Bar Code Labeling for Human Drug Products  
July 26, 2002**

**Presented by  
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Good morning Madam Chair, Commissioners, and Members of the Panel. I am Pamela Cipriano, PhD, RN, FAAN, Chief Clinical Officer, University of Virginia Health System and am representing the American Academy of Nursing and the American Organization of Nurse Executives. Thank you for the opportunity to discuss our concerns regarding patient safety and medical errors. The American Academy of Nursing, a subsidiary of the American Nurses Association, was established in 1973 to transform healthcare policy and practice through nursing knowledge. Today the Academy serves as the nursing profession's think tank. The American Organization of Nurse Executives, founded in 1967 is a subsidiary of the American Hospital Association and is comprised of registered nurses who design, facilitate, and manage care.

As front line health care workers, the nation's workforce of 2.7 million registered nurses have made and continue to make substantial contributions to reduce health care errors. The American Academy of Nursing (AAN) and the American Organization of Nurse Executives (AONE) embrace the development of point-of-care technologies that reduce medical errors and increase productivity, and appreciate the opportunity to discuss our view on the particular issue of bar code labeling for human drug products, biologicals, and devices.

A few weeks ago, the American Academy of Nursing, in conjunction with over 20 organizations, convened an interdisciplinary conference focused on using innovative technology to enhance patient care delivery. Nurses, pharmacists, physicians, hospital trustees, administrators, manufacturers, health policy analysts, architects, software engineers and others gathered in Washington, DC, July 12-14, 2002, to begin harnessing the strength of technology in redesigning the practice environment and care delivery system in order to improve nurse retention and health care quality. Conference participants supported the establishment of a system that:

- 1) utilizes technology to improve productivity and safety through automation,
- 2) improves medication administration processes, and
- 3) provides interactive, automatically recorded data at the point of care.

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The opportunity for error reduction with bar code labeling for human drug products, biologicals, and medical devices, promises to be significant. Bar codes, and other machine-readable codes are most effective when they are in a standard format, not yet

consistently found in health care applications. Bar coding is currently available to assist in the identification of patients, care givers, specimens, medications, and equipment. It further facilitates automated documentation, record keeping, billing, inventory tracking, and the study of "near misses" and errors.

Ensuring appropriate medication administration is a complex process involving a series of interrelated decisions and actions among a variety of professionals. Errors can occur at any point in the process. Automated information and decision support systems have proven effective in reducing many types of medical errors. More specifically, bar code technology can minimize the variation in the medication cycle and decrease medication errors. Use of bar coding automates the distribution, management, and control of medications. Such technology not only allows professional registered nurses to more accurately and efficiently administer medications, but it also streamlines nursing's workload -- thus allowing more time to be devoted to direct patient care activities. Studies indicate that bar code labeling of drugs in acute care settings can prevent over 7,000 deaths a year and save nearly \$4,700 per admission.

Further development and wide-scale deployment of bar coding require the health care industry to address issues of standardization of bar code technology, compatibility, reliability, and affordability. Keys to the successful application of such technology include:

- 1) Ensuring end-users are involved in the process from the beginning;
- 2) Creating integrated systems that do not require re-entry or re-keying of data; and
- 3) Reducing work load burden on nurses.

While the literature indicates that the mandated use of bar code labeling for human drug administration can provide substantial benefits to the quality and safety of patient care, there are certain aspects in the implementation of this technology that require further consideration. Areas demanding particular attention include but are not limited to patient populations, standardization, compatibility, reliability, and financial considerations.

Children are a population at risk for errors. The IOM noted that a four-year prospective quality assurance study found 315 medication errors resulting in injury among 2,147 neonatal and pediatric intensive care admissions. Many pediatric doses are non-standard, and are prepared internally by the pharmacy. A mechanism for adding a bar code label to institution specific medications may increase the cost of dose preparation, and adds time. Infant identification also presents challenges to bar coding given the size of the ID band. Systems that link mother to baby may have bar code labeling for the mother, but only manual identification for the infant. Full benefit of the use of technology is not realized.

A second area for further consideration is the standardization of the bar code technology. While we are pleased with forward movement toward developing appropriate standards for information exchange, the data and technology must be acceptable across the various settings. Nursing joins other organizations in support of the recommendations of the National Coordinating Council for Medication Error Reporting and Prevention asking for

bar coding of drugs to include the National Drug Code (NDC), lot/control/batch number and expiration date, at the unit-of-use package. Bar coding of drugs should also be possible for non-standard items at minimal cost to the dispensing pharmacy. This would include such preparations as ointments, lipids, TPN, manually prepackaged items, crash cart supplies, etc. Labeling of blood products should contain the donor, blood type, blood product, and intended patient. Administration of a drug or therapy would also be guided or assisted with bar coding of the patient's identification data. Wrist bands with bar coding can prevent an error by alerting the care giver to a mismatch between the patient and the intended drug or treatment.

Implementation of bar codes for medication control often succeed in decreasing errors related to wrong dose, wrong time, omitted doses, and transcription/order-entry. One Colorado hospital saw a drop between 33% and 52% in different types of medication errors after implementing a Point of Care information system for medication management. (Puckett, F. Medication-management component of a point-of-care information system. *Am J Health-Syst Pharm* 1995; 52:1305-1309) Bedside medication verification products have been on the market as a complete system for 2 years, however, some systems are still cumbersome and may cause an unreasonable increase in the time needed to administer medications. Nurses must have a reliable, accurate and rapid system that reduces workload and is more efficient or faster than current manual ones. One hospital discovered it had an 8 second delay in medication recognition and reconciliation with the patient's data base. Until discovered by administration, this unacceptable delay caused the nurses to circumvent the system. I must emphasize the importance of involving end-users in the development and implementation phases of this technology.

It is also desirable that manufacturers and suppliers of drugs and biologicals provide 100% of products with bar coding. This will ease the workload of not only nurses, but also pharmacists, also in short supply in the current and future work force.

Implementing standards for bar coding will introduce some challenges for existing equipment. Systems need maximum flexibility to support both existing hand-held scanner technology as well as machine-readable formats. Right now, many organizations are also challenged with having incompatible identification technologies. For example a blood gas analyzer that is equipped to read the magnetic identification strip on the care giver testing the specimen, cannot "read" the patient identification system which is in bar code format as the machine has not been adapted for bar code scanning and data capture.

The location of bar code labels on drugs needs to be adaptable to current technology such as robots that "pick" medications and fill medication carts. Transition to future 2-dimensional codes will also require a bridge from existing to new technology. These codes are very promising with high data density, redundant data, low contrast reading, and easy writing on conventional printers.

Further, the reliability of scanners to read the bar code is critical to the success of such technology. It has been found that some bar scanners cannot read curved surfaces. Since

almost all identification bracelets are on a wrist, valuable time can be spent flattening out the identification band to allow the scanner to recognize it, often requiring as much time as would be spent administering a medication without benefit of technology.

Finally, we must raise the issue of affordability and financing of such technology. Clearly the cost of implementation in practice settings will vary based on each institution and the structural changes required to manage point of care systems. Manufacturers and suppliers must share in the production of materials that respond to the mandate for safety and address work load burden. Collectively we have a duty to reduce error and prevent avoidable adverse events. Bar code labeling has proven beneficial for other advantages such as charge capture, billing, record keeping, inventory tracking and control, and automated documentation for patient records and quality improvement review.

In conclusion, we applaud the FDA's efforts to improve patient safety, and reduce the number of adverse drug events due to medication errors. Bar code labeling for human drug and biologic products is one means of applying simple technology to a broad spectrum of high risk processes and realizing a significant safety impact.

Thank you.